

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS
EASTERN DIVISION**

In Re *Ex Parte* Application of LUCIANO FASCINA, VLADIMORO BARBERIO, ANDREA TURCO, LUCA RAPALLO, REMUS ROBU, CHRISTIAN TROUCHOT, OLIVIER GESTAS, ADOLF HEINRICH, JOSE VICENTE TEMES ZAFRILLA, and MARY PIPER, IAN WAYNE PIPER, and MARK SHAUN PIPER, individually and as heirs and relatives of BARRY PIPER, for Judicial Assistance in Obtaining Evidence for Use in a Foreign Tribunal Under 28 U.S.C. § 1782.

Civil Action No. _____

**MEMORANDUM OF LAW IN SUPPORT OF *EX PARTE* APPLICATION FOR
JUDICIAL ASSISTANCE IN OBTAINING EVIDENCE FOR USE IN A
FOREIGN PROCEEDING UNDER 28 U.S.C. § 1782**

Pursuant to 28 U.S.C. § 1782, Luciano Fascina, Vladimoro Barberio, Andrea Turco, Luca Rapallo, Remus Robu, Christian Troughot, Olivier Gestas, Adolf Heinrich, Jose Vicente, Temes Zafrilla, and Mary Piper, Ian Wayne Piper, and Shaun Piper, individually and as heirs and relatives of Barry Piper (“Applicants”) request this Court’s assistance in obtaining evidence from Labcorp Bedford LLC, formerly known as Toxikon, LLC (“Toxikon”), for use in a civil action pending in Milan, Italy.

Background

Applicants are European citizens currently litigating a class action civil case against Philips RS North America, LLC and its European affiliates (collectively “Philips”) in the Civil Court of Milan in Italy. Declaration of Taryn E. Ourso (“Ourso Dec.”) ¶¶ 1-2, Ex. A.

Toxikon is not a party to the Italian lawsuit; its principal office is located in this District at 15 Wiggins Avenue, Bedford, Massachusetts. Ourso Dec. ¶¶ 4-6, Exs. B & C.

A. The Italian Litigation

Applicants sued Philips in the Court of Milan on behalf of all European Union and United Kingdom citizens who used certain Philips-manufactured CPAP (continuous positive airway pressure), BiPAP (bilevel positive airway pressure), and mechanical ventilator devices from approximately 2008 to April 2021. *See* Ourso Dec., Ex. A. These devices pump dry ambient air into the device user's throat and nose. *Id.*, Ex. A ¶ 209. Philips placed polyurethane foam in the devices to dampen the noise of electric motors pumping air inhaled by the device user. *Id.*, Ex. A ¶ 212.

Applicants allege this polyurethane foam disintegrated under normal use conditions, sending gas and particulate matter into the noses and mouths of users that was and is genotoxic, cytotoxic, and carcinogenic. *Id.*, Ex. A ¶¶ 44, 260. This put device users at serious risk of injury and clinical deterioration. *Id.*, Ex. A ¶ 322. Applicants allege that as early as 2008, when the foam was first used in these devices, Philips began receiving reports of defects related to the foam; however, it continued to sell the devices anyway, without telling users about the potential health risks until April 2021, when it was ready to market and sell its new Dreamstation 2 CPAP device. *Id.*, Ex. A ¶¶ 261, 341-46.

B. Toxikon's 2008 Cytotoxicity Test

In June 2008, the year the devices were first sold, Toxikon issued a report on a cytotoxicity test of the polyurethane foam Philips used in the devices. Excerpts from that

report were published by the Pittsburgh Post-Gazette in July 2024:¹

2008 test showed foam used in Philips breathing devices was cytotoxic

Below are excerpts from a June 13, 2008, cytotoxicity test of the foam used inside the CPAP breathing machines.



TOXIKON FINAL GLP REPORT: 08-2417-G1

L929 MEM ELUTION TEST – ISO

Test article

Polymer Technologies Foam PAFS4-BU

Author

Franck Grall, Pharm.D., Ph.D.

Final Report Date

June 13, 2008

Performing Laboratory

Toxikon Corporation, 15 Wiggins Ave., Bedford, MA 01730

Sponsor

Respironics, Incorporated, 365 Plum Industrial Court,
Pittsburgh, PA 15239

STUDY SUMMARY

Severe biological reactivity (Grade 4) was observed in the L929 mammalian cells at 48 hours post exposure to the test article extract. The observed cellular response obtained from the positive control article extract (Grade 4) and negative control extract (Grade 0) confirmed the suitability of the test system.

Based on the criteria of the protocol, the test article, Polymer Technologies Foam PAFS4-BU, is considered cytotoxic and does not meet the requirements of the Elution Test, ISO 10993–5 guidelines.

Highlighted, bold emphasis added. Recreated from original documents

Source: Internal Philips records

James Hilston/Post-Gazette

The report indicates the foam was cytotoxic.

Plaintiffs in the United States sued Philips after a June 2021 recall of these devices; the court recently approved a settlement in that case. *In re Philips Recalled CPAP, Bi-Level PAP, & Mech. Ventilator Prods. Litig.*, No. MC 21-1230, 2024 WL 4988339, at *1 (W.D. Pa.

¹ *Inside the raging battle at Philips: Internal fights and resignations over dangerous breathing machines*, POST-GAZETTE.COM, <https://www.post-gazette.com/news/health/2024/07/07/philips-respironics-cpap-breathing-machines/stories/202407070070> (last visited Feb. 18, 2025); Ourso Dec. ¶ 7.

Dec. 5, 2024). ProPublica and the Pittsburgh Post-Gazette have reported extensively on the dangerous defects caused by the polyurethane foam and on efforts by Philips to conceal the defects from device users.²

Discovery Requested

Unless a court order allowing discovery under § 1782 prescribes otherwise, “the document or other thing produced [shall be] in accordance with the Federal Rules of Civil Procedure.” 28 U.S.C. § 1782(a). *See also Sandra Holding Ltd. v. Al Saleh*, No. 18-mc-91406-PBS, 2019 WL 3072197, at *4 (D. Mass. July 15, 2019) (“Section 1782 requires discovery orders to be ‘in accordance with the Federal Rules of Civil Procedure’ unless the court should order otherwise.”). Under the Federal Rules of Civil Procedure, a party “may obtain discovery regarding any nonprivileged matter that is relevant to any party’s claim or defense and proportional to the needs of the case[.]” Fed. R. Civ. P. 26(b)(1). Rule 26 is “construed broadly to encompass any matter that bears on, or that reasonably could lead to other matters that could bear on, any issue that is or may be in the case.” *Oppenheimer Fund, Inc. v. Sanders*, 437 U.S. 340, 351 (1978).

Pursuant to 28 U.S.C. § 1782, Applicants request an order allowing the following document discovery from Toxikon for use in the Italian proceedings:

² *See, e.g., Philips kept complaints about dangerous breathing machines secret while company profits soared*, POST-GAZETTE.COM, <https://newsinteractive.post-gazette.com/philips-respironics-cpap-defect-recall/index.php> (Sept. 27, 2023) (last visited Feb. 18, 2025); *Philips Kept Complaints About Dangerous Breathing Machines Secret While Company Profits Soared*, PROPUBLICA.ORG, <https://www.propublica.org/article/philips-kept-warnings-about-dangerous-cpaps-secret-profits-soared> (Sept. 27, 2023) (last visited Feb. 18, 2025); *Top Philips Executive Approved Sale of Defective Breathing Machines by Distributors, Despite Tests Showing Health Risks*, PROPUBLICA.ORG, <https://www.propublica.org/article/philips-executive-defective-breathing-machines> (Oct. 27, 2023) (last visited Feb. 18, 2025).

- (1) A complete copy of the June 2008 report issued by Toxikon titled “Toxikon Final GLP Report: 08-2417-G1,” a portion of which was published by the Pittsburgh Post-Gazette in July 2024.
- (2) All non-privileged written communications (i.e., faxes, letters, emails) exchanged between and/or among Toxikon, Philips, and/or Polymer Technologies Inc. related to the June 2008 report issued by Toxikon titled “Toxikon Final GLP Report: 08-2417-G1.”

Applicants intend to use this document in the Italian litigation to help prove that the polyurethane foam contained in certain CPAP, Bi-PAP, and mechanical ventilator devices was and is cytotoxic and that Philips had been aware of that cytotoxicity since at least 2008 when the report was issued. Ourso Dec. ¶ 3. This request is straightforward, narrowly tailored, and plainly relevant to Applicants’ claims against Philips.

Argument & Authorities

Under 28 U.S.C. § 1782, “[t]he district court of the district in which a person resides or is found may order him to give his testimony or statement or to produce a document or other thing for use in a proceeding in a foreign or international tribunal . . . upon the application of any interested person.” *See also In re Schlich*, 893 F.3d 40, 46 (1st Cir. 2018). If an applicant establishes the statute’s requirements, a court may allow the requested discovery if the balance of four discretionary factors found in *Intel Corp. v. Advanced Micro Devices, Inc.*, 542 U.S. 241, 256 (2004), (the “*Intel* factors”) favors disclosure. Here, Applicants meet the statute’s requirements, and *Intel*’s discretionary factors weigh in favor of allowing the requested discovery.

A. Applicants meet the statutory requirements of 28 U.S.C. § 1782.

A district court may grant discovery pursuant to 28 U.S.C. § 1782 if the following statutory requirements are met: “(1) the person from whom discovery is sought ‘resides or is

found’ in the district where the court sits; 2) the request seeks evidence (the ‘testimony or statement’ of a person or the production of a ‘document or other thing’) ‘for use in a proceeding in a foreign or international tribunal’; 3) the request is made by a foreign or international tribunal or by ‘any interested person’; and 4) the material sought is not protected by ‘any legally applicable privilege.’” *In re Schlich*, 893 F.3d at 46. If these statutory requirements are met, the district court “is authorized, but not required, to provide judicial assistance by permitting discovery.” *Id.* (citing *Intel Corp.*, 542 U.S. at 247).

Applicants have established the statutory requirements. *First*, Toxikon resides and is found in this District because its principal office is in Bedford, Massachusetts. Ourso Dec. ¶ 5, Ex. B. *Second*, Applicants seek limited discovery from Toxikon for use in litigation currently pending in Milan, Italy. *Id.* ¶ 3. *Third*, Applicants are litigants and parties to the foreign proceeding, therefore they are interested persons. *See, e.g., Intel Corp.*, 542 U.S. at 256 (“No doubt litigants are included among, and may be the most common example of, the ‘interested person[s]’ who may invoke § 1782.”). *Finally*, the test report Applicants seek from Toxikon has already been divulged to the Pittsburgh Post-Gazette, and a portion of it has been published and disseminated to the general public. Ourso Dec. ¶ 7. Further, Applicants seek only nonprivileged communications related to the report. Therefore, the requested discovery is not privileged, and in any event, Toxikon may raise any applicable privilege in response to Applicants’ discovery request. *See In re Fagan*, No. 19-mc-91210-ADB, 2019 WL 2267063, at n.1 (D. Mass. May 28, 2019) (“Even if the Court were to grant the application, the subpoenaed entities would still be afforded an opportunity to object and move for a protective order to the extent privileged information was implicated.”). Accordingly,

Applicants meet the statutory criteria of 28 U.S.C. § 1782.

B. *Intel's* discretionary factors weigh in favor of granting discovery.

In *Intel Corp. v. Advanced Micro Devices, Inc.*, the Supreme Court identified four discretionary factors for district courts to consider when deciding whether to grant a § 1782 application for discovery: (1) whether the person from whom discovery is sought is a party to the foreign proceeding, in which case “the need for § 1782(a) aid generally is not as apparent”; (2) “the nature of the foreign tribunal, the character of the proceedings underway abroad, and the receptivity of the foreign government or the court or agency abroad to U.S. federal-court judicial assistance”; (3) whether the request “conceals an attempt to circumvent foreign proof-gathering restrictions or other policies of a foreign country or the United States”; and (4) whether the request is “unduly intrusive or burdensome.” *Intel Corp.*, 542 U.S. at 264-65. *See also, e.g., In re Schlich*, 893 F.3d at 46-47.

i. Factor One: Toxikon is not a party to the Italian lawsuit.

Generally, when an applicant requests evidence from “a nonparticipant in the matter arising abroad,” the need for § 1782 aid is apparent. *Intel Corp.*, 542 U.S. at 264. That is because “nonparticipants in the foreign proceeding may be outside the foreign tribunal’s jurisdictional reach; hence, their evidence, available in the United States, may be unobtainable absent § 1782 aid.” *Id.*

Toxikon is not a party to the litigation pending in Milan, Italy, therefore the first *Intel* factor weighs in favor of granting the Application. *See Chevron Corp. v. Shefftz*, 754 F. Supp. 2d 254, 261 (D. Mass. 2010) (first *Intel* factor “weigh[ed] heavily in favor of granting discovery” where foreign tribunal lacked jurisdiction over respondent).

ii. **Factor Two: Applicants can submit evidence obtained under § 1782 to the Court of Milan.**

The second *Intel* factor, which considers the foreign court's receptivity to U.S. federal-court judicial assistance, also weighs in favor of granting the Application. As to this factor, courts "have been instructed to tread lightly and heed only clear statements by foreign tribunals that they would not welcome § 1782 assistance." *In re Porsche Automobile Holdings SE*, No. 19-mc-91129-LTS, 2019 WL 5806913 at *7 (D. Mass. Nov. 6, 2019).

Indeed, district courts throughout the country have granted § 1782 discovery applications for use in Italian proceedings, including in the Court of Milan where Applicants would use evidence obtained from Toxikon. *See, e.g., In Re Caterpillar, Inc.*, No. 3:19-mc-0031, 2020 WL 192327 (M.D. Tenn. Apr. 21, 2020) (second *Intel* factor favored § 1782 request for documents for use in the Court of Milan); *INVISTA North America S.a.r.l. v. Me&G USA Corp.*, No. 11-1007-SLR-CJB, 2013 WL 1867345 (D. Del. Mar. 28, 2013) (second *Intel* factor favored discovery of documents for use in Italian patent infringement proceeding); *In re China Constr. Bank (Asia) Corp. Ltd.*, No. 23-MC-17 (JMF), 2023 WL 3791711 (S.D.N.Y. June 2, 2023) (allowing discovery for use in Italian proceedings pursuant to § 1782); *In re Eni S.p.A.*, No. 20-mc-334-MN, 2021 WL 2985171 (D. Del. July 15, 2021) (discovery properly granted under § 1782 for use in Italian proceeding); *In re Republic of Kazakhstan for an Ord. Directing Discovery from Wells Fargo Bank, Nat'l Ass'n Pursuant to 28 U.S.C. § 1782*, No. 18-CV-409 (DWF/TNL), 2021 WL 3561364 (D. Minn. Aug. 12, 2021) (all *Intel* factors weighed in favor of granting § 1782 discovery request for use in Italian proceedings).

Unlike American federal courts, Italian courts do not have a pre-trial discovery process for obtaining documents. Rather, the parties submit documentary evidence to the

judge, who then decides whether to take the documents into account when deciding the case. *See* Simona Grossi, *A Comparative Analysis Between Italian Civil Proceedings and American Civil Proceedings Before Federal Courts*, 20 Ind. Int'l & Comp. L. Rev. 213, 218-229 (2010). In Italy, a party is not required to lay a foundation, prove authenticity, or show relevance to move a document into evidence because the judge “is free to decide which exhibits . . . to consider and, in general, which evidence on file is more suitable to support the decision.” *Id.* at 224. Accordingly, Applicants can submit documentary evidence to the Italian judge in support of their case, including evidence obtained from Toxikon in this District. Ourso Dec. ¶ 8. Therefore, the second *Intel* factor weighs in favor of granting the requested discovery.

iii. Factor Three: Applicants seek discovery under § 1782 because Toxikon is not subject to jurisdiction in Italy.

The third *Intel* factor queries whether Applicants seek to use 28 U.S.C. § 1782 to circumvent proof gathering restrictions. This factor does not require Applicants to “seek the foreign court’s blessing . . . The inquiry here is whether the discovery is being sought in bad faith.” *In re General Electric Co.*, No. 1:22-cv-91125-IT, 2022 WL 16720425, at *6 (D. Mass. Nov. 4, 2022) (quoting *Chevron Corp.*, 754 F. Supp. 2d at 262); *see also In re Valitus, Ltd.*, No. 20-mc-91133-FDS, 2020 WL 6395591, at *8 (D. Mass. Nov. 2, 2020) (applicant entitled to seek relevant discovery under § 1782 even though it was unable to obtain it under foreign procedures). There is no foreign discoverability requirement. *See, e.g., In re Porsche Automobile Holding SE*, 2019 WL 5806913, at *8 (citing *Intel Corp.*, 542 U.S. at 253).

Here, the evidence Applicants seek from Toxikon is located in this District. This evidence is relevant to Applicants’ case because it shows the foam used in the breathing

devices at issue was and is cytotoxic and that Philips had been aware of that toxicity as early as 2008. Ourso Dec. ¶ 7. Neither § 1782 nor the third *Intel* factor require Applicants to first seek discovery from Toxikon in Italy, and neither Italian law nor the Court of Milan restricts Applicants from obtaining evidence here under § 1782.³ *Id.* ¶ 9. Additionally, Toxikon is not a party to the Italian case, nor is it subject to the Court of Milan’s jurisdiction. By seeking evidence from Toxikon in the United States, Applicants do not act in bad faith; rather, they seek a narrow body of highly relevant evidence to help prove their case in Italy. *See, e.g., Chevron Corp.*, 754 F. Supp. 2d at 262 (third *Intel* factor weighed in favor of discovery where applicant’s discovery request “appears to be a good faith effort to elicit evidence that has probative value in [foreign] proceedings”). Therefore, Applicants appropriately seek discovery under § 1782, which is designed for this type of situation—to effectuate discovery of evidence located in the United States for use in a foreign proceeding. Accordingly, this factor weighs in favor of granting the Application.

iv. Factor Four: Applicants request minimal evidence from Toxikon.

The fourth *Intel* factor addresses whether a § 1782 request is “unduly intrusive or burdensome to the extent that it should either be trimmed or rejected outright.” *See In re Schlich*, 893 F.3d at 47 (internal quotation marks omitted). Applicants need only one report from Toxikon and the non-privileged written communications relating to it. The report shows the foam used in Philips’s devices was cytotoxic, and it was partially published online

³ *See also Intel Corp.*, 542 U.S. 241, at n.12 (“Most civil-law systems lack procedures analogous to the pretrial discovery regime operative under the Federal Rules of Civil Procedure. . . . The drafters [of § 1782] were quite aware of the circumstance that civil law systems generally do not have American type pretrial discovery, and do not compel the production of documentary evidence.”) (cleaned up).

and shared with the Pittsburgh Post-Gazette. Ourso Dec. ¶ 7. Additionally, communications related to the report will support Applicants' claim that Philips had been aware of the cytotoxicity of the polyurethane foam used in its devices since as early as 2008. *Id.* ¶ 3. Because Applicants' request is relevant, narrowly tailored, and unimposing, this factor weighs in favor of granting the Application.

Conclusion

Applicants satisfy the requirements of 28 U.S.C. § 1782, and the discretionary *Intel* factors weigh in favor of granting the requested discovery. The discovery sought is relevant to litigation pending in Milan, Italy, between Applicants and Philips. Therefore, Applicants respectfully ask the Court to grant their Application and issue an order authorizing them to issue the subpoena attached to the Application.

DATED: March 31, 2025

/s/ Susan M. Ulrich

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